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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,913	03/16/2004	Katsuhiko Hiejima	NPR-154	9625
20374	7590	01/10/2008		
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER STEPHENS, JACQUELINE F	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,913

Applicant(s)

HIEJIMA ET AL.

Examiner

Jacqueline F. Stephens

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/16/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 7-12 is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/07 has been entered.

Response to Arguments

2. Applicant's arguments filed 10/16/07 have been fully considered but they are not persuasive. Applicant argues Elias does not show the transferring passage extends through the entire longitudinal length. However, Applicant has not specified in the claims through which longitudinal length. The claim can be interpreted as the entire longitudinal length of the intermediate portion of the valve, etc. Applicant argues elements 18a are not branch portions. The Examiner has identified element 18 as equivalent to the spike of the present invention. Similarly, Applicant argues the helical spring of Elias, identified by the Office as being a plurality of divided bodies comprising the spike is not formed in one pair in axial symmetry. Figure 3 of Elias shows elements 18A as or, as broadly as claimed branches or divided bodies formed on element 18. Applicant has not set forth why these elements are deficient to describe the claimed

invention. Applicant argues the spike has a solid structure. The Examiner maintains the spike is solid as broadly as claimed, as compared to a liquid structure.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Elias et al. USPN 5549566.

As to claim 3, Elias discloses a medical valve 12, to which a male luer is to be separably connected (col. 3, lines 57-58), comprising: (a) a housing 14 having a hollow body opened at the top end 24, wherein the tip of the male luer is to be removably inserted in the housing; (b) a longitudinal solid spike 18 disposed to extend longitudinally in the housing, the spike except at least the top end portion being formed in an approximately tapered shape (Figures 1 and 2) in which its outside diameter becomes progressively smaller toward the top end portion, wherein a fluid transferring passage 68 extends the entire longitudinal length of the spike 18 (Figures 1 and 2). Elias discloses a groove-shaped fluid transferring passage (Figures 1-4, defined by ribs 56). The fluid transferring passage is opened radially outwardly, is formed to extend the entire longitudinal length in the peripheral surface of the spike, the bottom portion of the fluid transferring passage 66 being connected to a fluid circuit (col. 5, lines 43-45); and

(c) an elastic seal 16 having an elastically deformable tubular shape fitted on the spike to seal the spike, the elastic seal comprising a top end portion 46 having an openable/closable portion 50 to be openably closed over the spike, wherein the elastic seal is elastically deformed to be downwardly shrunk by downward pressure due to the tip of the male luer, thereby the openable/closable portion 50 is brought into abutment with the spike, and is elastically deformed to be opened radially outwardly to be fitted onto the spike, so that the inside of the male luer communicates with the fluid transferring passage of the spike (col. 3, line 57 through col. 4, line 7; col. 4, lines 61-65). The limitations regarding compression of the seal is directed to an intended use of the article. Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). If the prior art structure is capable of performing the intended use, then it meets the claim limitations. Elias discloses a joining portion 50a constituting the top end portion of the spike; and a plurality of longitudinal branch portions 18a, which constitutes the remaining portion of the spike, formed integrally with the joining portion and extending downwardly from the joining portion, and wherein the fluid transferring passage is defined between the branch portions (Figure 3).

As to claim 4, Elias discloses a medical valve, see the rejection of claim 3, supra. Elias discloses the longitudinal spike 18 comprises a plurality of longitudinal divided bodies 80 which are formed into one pair in axial symmetry and extend longitudinally along the

Art Unit: 3761

entire longitudinal length of the spike, and wherein the fluid transferring passage 68 is defined between the divided portions and an inner surface of the elastic seal 16 (Figures 5 and 6).

As to claim 5, see the rejection of claim 3, supra. Elias discloses a plurality of main portions formed by ridges 56 (Figure 4). A bridge portion (interior of the longitudinal spike) is formed integrally with the main portions and disposed between the main portions to join the main portions together, wherein the fluid transferring passage 68 is defined between the main portions and an inner surface of the elastic seal 16.

As to claim 6, see the rejection of claim 3, supra. Elias discloses the spike 18 has an approximately cylindrical shape and solid structure, the top end surface of the spike (Figure 3, at spike top 62 abutting 50a), being an approximately hemispherical surface, which is upwardly convex, the spike except the top end portion being formed in an approximately tapered shape in which the outside diameter becomes progressively smaller toward the top end.

Allowable Subject Matter

5. Claims 2, 7-12 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jacqueline F Stephens
Primary Examiner
Art Unit 3761

December 27, 2007